Study No.:
_____

SUMMARY SAFEGUARD STATEMENT
(To be completed by all investigators employing human subjects in research)

Title: Indiana Oral Health Survey, 1992-1993

IF ADDITIONAL SPACE FOR RESPONSES IS DESIRED, THIS DOCUMENT MUST BE RETYPED ONTO PLAIN PAPER MAINTAINING THE IDENTICAL FORMAT AND EXACT QUESTION WORDING WHILE ADDING EXTRA SPACE WHERE NEEDED.
(Do not type on the reverse side of any forms.)

I.A. Briefly describe the general nature and purpose of the research proposal:

As is well documented, the prevalence of dental disease in children residing in Indiana is on the decline. Although previous dental health surveys have been more general in scope and focused on schoolage children, scant information is available to concerning the prevalence of dental disease among schoolchildren from minority races or preschool children.

The purpose of this investigation is to collect data concerning the oral health status of children residing in eleven counties in the state of Indiana. These counties have been chosen because they have significant Black and other minority populations. Approximately 1,500 schoolchildren (ages 6, 7, 8, and 15) as well as oral health of these previously neglected populations can be made.

I.B. Check appropriate line telling site of performance: ___Carter, ___Riley, ___Wishard, ___University, ___Veterans, _X_Other (specify location:) Indiana State Board of Health

I.C. List specific eligibility requirements for subjects, including those criteria which would exclude otherwise acceptable subjects, telling how they will be recruited.

1, parents must read and sign an informational letter of consent;
2, parents must complete a medical history questionnaire;
3, child must be good health and not have any medical conditions which would require additional precautions be taken prior to a dental examination;
4, allow the performance of battery of dental examinations to assess the health of the dental hard and soft tissues;
5, provide data by means of a questionnaire concerning family demographics and oral health care; and
6, be available for an examination.

I.D. Check appropriate line for subject population involved where it includes: X__minors, ___fetuses, ___abortuses, ___pregnant women, ___mentally disabled, ___prisoners, ___economically or educationally disadvantaged. If any of the above are used, state the necessity for doing so.

Purpose of the investigation is to assess the dental health of minors in Indiana.

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SUMMARY SAFEGUARD STATEMENT (Cont'd)

I.E. List all procedures to be used on human subjects. **ASTERISK** those you consider experimental. For the asterisked procedures, describe the usual method(s), if any, that were considered and why there were used.

1, collection of informed consent;
2, collection of medical history data;
3, collection of demographic and health care practices information by means of a questionnaire; and,
4, oral examinations to determine the prevalence of dental caries, gingivitis, nursing bottle caries, and fluorisis.

I.F. State the potential risk—for example, physical, psychological, social, legal or other—connected with the proposed procedures.

1, risk of physical injury or trauma related to the performance of a dental examination;
2, risk of cross-contamination; and,
3, loss of records confidentiality.

I.G. Describe procedures (including methods to assure confidentiality) for protecting against, or minimizing potential risks. Assess their likely effectiveness.

Dental examinations will be performed by an experienced dental examiner. All examination procedures will be performed using the guidelines as set forth by the Infection Control Committee of the School of Dentistry to reduce the likelihood of disease transmission. All records and data generated by the investigation will be stored in locked cabinets with access limited to those directly involved in the investigation. These precautions should limit the panelist risk to minimal level.

II.A. What, if any, benefit is to be gained by the subject? In the event of monetary gain, include all payment arrangements (amount of payment and the proposed method of disbursement), including reimbursement of expenses. Explain if there will be any partial payment if the subject withdraws prior to completion of the study.

Subjects will receive a free dental examination, oral hygiene products and dental health brochures. If a child is found to be in immediate need of dental care, the principal investigator will notify the child's parents as to the nature of the problem and the need for immediate treatment.

II.B. What information may accrue to science or society in general as a result of this work?

The results of this survey will likely serve as the foundation for future dental health programs in the State of Indiana and will allow government officials to determine if the State is in compliance with Health Care Objectives for the Year 2000.

II.C. Briefly describe how risks to subjects are reasonable in relation to anticipated benefits.

Based in the precautions to be taken, the risk is considered to be minimal as are the benefits to the panelists. The data resulting from the investigation will be of moderate benefit to state planning agencies.

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SUMMARY SAFEGUARD STATEMENT (Cont'd)

II.D. Will you be using the facilities of the General Clinical Research Center, University Hospital, Rm. N-597, 274-4356? Yes:___ No:_X_. If yes, will it be for __inpatient or __outpatient use?

III. If the study involves the use of new drugs or devices, the following information is required by the Food and Drug Administration:

III.A. Name of Drug Sponsor:__N/A_____

IND Number:_____Phase I, II, or III Study:_____

III.B. Name of Device Manufacturer:___N/A_____

IDE Number:_____Significant Risk:_____Nonsignificant Risk:_____

The IRB is required to determine whether or not the device is significant risk. Please provide appropriate documentation and the investigator's assessment of the device risk.

IV.A. List the Principal Investigator and any coinvestigators. If you anticipate that another department may be involved in this research, include a coinvestigator from that department or a letter of cooperation indicating the department's willingness to be involved in this study. (If there are multiple investigators, please indicate only one person as the principal investigator, others should be designated as co-investigators.)

Mark E. Mallat, DDS	Principal Investigator
Charles Smith, DDS	Co-investigator
Bradley B. Beiswanger, DDS	Co-investigator